

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of)	· ICOLIVEL
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RUNGE et al.)	TECH CENTER 1600/2000 #12
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Serial No. 09/673,136)	
Filed: April 29,1999)	7/21/03
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For: DRY MICROORGANISM CULTURES AND THEIR PREPARATION

DECLARATION

I, Hans-Peter Harz, Dr.-Ing., a citizen of the Federal Republic of Germany and residing at 67373 Dudenhofen, Federal Republic of Germany, declare as follows:

I am a fully trained chemical engineer, having studied chemical engineering at the University Karlsruhe from 1976 to 1987.

I am well acquainted with technical English.

I joined BASF Aktiengesellschaft of 67056 Ludwigshafen, Federal Republic of Germany in 1988; since 1990 I have been working on developments in food and feed additives.

I am co-inventor of the invention disclosed and claimed in Application Serial No. 09/673,136, and the field, to which the said application relates, and with the Examiner's objections, according to which the invention as claimed lacks inventiveness.

The present invention relates to novel dey microorganism cultures and methods for their preparation.

In order to further illustrate the invention the following experiment has been carried out:

- 1. **Table A** shows the composition of four different compressed microorganism preparations which have been produced according to the present invention via spray-drying the microorganisms, further drying the spray-dried product and subsequent compression of the dried powder. Different linear forces have been applied. Starting material and compressed dried product have been analyzed for their cfu-values. The survival rate (in %) as well as the abraded material (in %) was determined.
- 2. Results are summarized in **Table B.** The obtained data show that according to the present invention compressed microorganism cultures may be prepared which, even after said compression step, show surprisingly valuable cfu-values. Moreover, the obtained products surprisingly are also mechanically very stable. A content of abraded material of less than 20 % (rotating the compressed product for 20 minutes in a plexiglas cylinder) illustrate sufficient mechanical stability in order to avoid the problem of dust formation.
- 3. In particular it was observed according to the present invention that a thorough control of the humidity within the dried products (compressed or non-compressed) of the present invention surprisingly results in products of improved storage stability. For this purpose, it is important to use for the preparation of the products a conditioned, dry gas having a dew point of less than about +5°C, and optionally to perform a further drying step. By these steps the residual humidity may be significantly reduced resulting in a dried product of improved storage stability. The influence of residual humidity of a dried powder on storage stability is illustrated by the results of storrage experiments summarized in Table C. As can be taken from said table, a reduction of residual humidity in the spray dried product significantly increases its storage stability. Table D illustrates the correlation between residual humidity and parameter aw (water activity) described in the present specification.
- The above data illustrate that by following the teaching of the present invention dry microorganism cultures are available which are characterized by
 - a superior content of viable cells of the microorganism(s),
 - a superior survival rate after compression,
 - a high mechanical stability and
 - a superior storage stability.

Obtaining a dried microorganism culture showing said <u>combination</u> of advantageous features was surprising to me in the light of the prior art knowledge at the time the present invention was made.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed at 67056 Ludwigshafen, Germany, this. 10.day of ... April 2003

Hans-Peter Harz